

60th Medical Group (AMC), Travis AFB, CA
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20130029A

DATE: 2 December 2013

PROTOCOL TITLE: Comparative testing of hemostatic dressings in a large animal model (*Sus scrofa*) with severe hepatic injuries

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Hilary Gallogly

DEPARTMENT: Clinical Investigations Facility

PHONE #: 423-7400

INITIAL APPROVAL DATE: 24 April 2013

LAST TRIENNIAL REVISION DATE: N/A

FUNDING SOURCE: Air Force Surgeon General's Office

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
<i>Sus scrofa</i>	36	18	18
Note. Many fewer animals than approved were used because one of the original treatment groups (Lypressin-soaked gauze) could not be done due to the drug not being available. The remaining 3 treatment groups had only 6 animals per group instead of 9 because it became apparent that there was no difference between treatments and early stopping rules were applied.			

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

<input type="checkbox"/> Training: Live Animal	<input type="checkbox"/> Medical Readiness	<input type="checkbox"/> Prolonged Restraint
<input type="checkbox"/> Training: non-Live Animal	<input type="checkbox"/> Health Promotion	<input type="checkbox"/> Multiple Survival Surgery
<input type="checkbox"/> Research: Survival (chronic)	<input type="checkbox"/> Prevention	<input type="checkbox"/> Behavioral Study
<input checked="" type="checkbox"/> Research: non-Survival (acute)	<input type="checkbox"/> Utilization Mgt.	<input type="checkbox"/> Adjuvant Use
<input type="checkbox"/> Other ()	<input checked="" type="checkbox"/> Other (Treatment)	<input type="checkbox"/> Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ☐ C ☒ D ☐ E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

☐ Inactive, protocol never initiated

☐ Inactive, protocol initiated but has not/will not be completed

☒ Completed, all approved procedures/animal uses have been completed

5. FUNDING STATUS: Funding allocated: \$20,160.00 Funds remaining: \$ 0.00

6. PROTOCOL PERSONNEL CHANGES:

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? ☒ Yes ☐ No

Report Documentation Page		Form Approved OMB No. 0704-0188
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1. REPORT DATE 19 DEC 2013	2. REPORT TYPE Final	3. DATES COVERED 24 Apr 2013 - 19 Dec 2013
4. TITLE AND SUBTITLE FDG20130029A "Comparative testing of hemostatic dressing in a large animal model (Sus Scorofa) with severe hepatic injuries."		5a. CONTRACT NUMBER
		5b. GRANT NUMBER
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) Capt. Hilary Gallogly		5d. PROJECT NUMBER FDG20130029A
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Clinical Investigation Facility David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535		8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Clinical Investigation Facility David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535		10. SPONSOR/MONITOR'S ACRONYM(S)
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release, distribution unlimited		
13. SUPPLEMENTARY NOTES		
14. ABSTRACT <p>OBJECTIVES: We compared the hemostatic and hemodynamic effects of dilute concentrations of epinephrine soaked gauze and with epinephrine soaked Combat Gauze (CG) in swine with grade IV liver injuries. METHODS: Anesthetized swine were instrumented, splenectomized, and had a grade IV liver injury created. After 30 seconds of free bleeding, damage control liver packing was performed with laparotomy pads soaked in different concentrations of epinephrine (1 mg/L or 2mg/L normal saline) or CG pads soaked in 3mg epinephrine/L normal saline. Hemodynamic and laboratory data were recorded, and blood loss was measured for two hours. Post-mortem histopathology was performed on the liver injury sites. RESULTS: There were no pre-injury differences between groups, and all animals survived the entire two hours. Animals treated with 1 mg/L epi, 2 mg/L epi, and 3 mg/L epi-CG dressings had similar amounts of blood loss (18.7, 22.3, and 21.8 mL/kg respectively, $p = 0.85$). There were no significant differences between groups in laboratory measurements or physiology measurements. Histopathology revealed no adverse cellular effects from any treatment. CONCLUSION: There were no significant or practical differences in blood loss from animals treated with 1 mg/L and 2 mg/L epinephrine. In a previous experiment, we found that 3 mg/L epinephrine soaked gauze resulted in much less blood loss (16.5 mL/kg) and those animals had similar heart rates and mean arterial pressures as those we observed in this study. Using the more concentrated epinephrine solution with Combat Gauze did not offer any advantage over plain gauze with epinephrine. Therefore, we recommend using a more concentrated epinephrine solution (3 mg epinephrine per liter sterile saline) as a hemostatic dressing in severe liver injuries.</p>		
15. SUBJECT TERMS US Air Force, Medical Service, Medical Research, Graduate Medical Education		

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 3	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Capt Paul Vu, AI-Surgeon, approved by the IACUC on 9 September 2013.

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

7. PROBLEMS / ADVERSE EVENTS: Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

8. REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

9. PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

Submitted for presentation at the Society of Air Force Clinical Surgeons annual meeting.

10. Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?

Yes. The protocol outcomes will help guide therapeutic choices for Air Force surgeons operating on liver injuries.

11. PROTOCOL OUTCOME SUMMARY: (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

OBJECTIVES: We compared the hemostatic and hemodynamic effects of dilute concentrations of epinephrine soaked gauze and with epinephrine soaked Combat Gauze™ (CG) in swine with grade IV liver injuries.

METHODS: Anesthetized swine were instrumented, splenectomized, and had a grade IV liver injury created. After 30 seconds of free bleeding, damage control liver packing was performed with laparotomy pads soaked in different concentrations of epinephrine (1 mg/L or 2mg/L normal saline) or CG pads soaked in 3mg epinephrine/L normal saline. Hemodynamic and laboratory data were recorded, and blood loss was measured for two hours. Post-mortem histopathology was performed on the liver injury sites.

RESULTS: There were no pre-injury differences between groups, and all animals survived the entire two hours. Animals treated with 1 mg/L epi, 2 mg/L epi, and 3 mg/L epi-CG dressings had similar amounts of blood loss (18.7, 22.3, and 21.8 mL/kg respectively, $p = 0.85$). There were no significant differences between groups in laboratory measurements or physiology measurements. Histopathology revealed no adverse cellular effects from any treatment.

CONCLUSION: There were no significant or practical differences in blood loss from animals treated with 1 mg/L and 2 mg/L epinephrine. In a previous experiment, we found that 3 mg/L epinephrine soaked gauze resulted in

much less blood loss (16.5 mL/kg) and those animals had similar heart rates and mean arterial pressures as those we observed in this study. Using the more concentrated epinephrine solution with Combat Gauze™ did not offer any advantage over plain gauze with epinephrine. Therefore, we recommend using a more concentrated epinephrine solution (3 mg epinephrine per liter sterile saline) as a hemostatic dressing in severe liver injuries.


(Principal Investigator Signature)

20 February 2014
(Date)